

PATENT
Customer No. 22,852
Attorney Docket No. 02356.0080-01

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
DE REUSE et al.) Group Art Unit: Unassigned
Application No.: 10/720,470) Examiner: Unassigned
Filed: November 25, 2003)
For: METHODS OF INHIBITING)
HELICOBACTER PYLORI)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(b), applicants bring to the attention of the Examiner the documents listed on the attached PTO 1449. This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits for the above-referenced application.

Copies of the listed documents were previously submitted in a prior application, Application No. 09/742,361, filing date December 22, 2000, upon which applicants rely for the benefits provided in 35 U.S.C. § 120. Applicants respectfully request that the Examiner consider the listed documents and indicate that they were considered by making appropriate notations on the attached form.

FINNEGAN
HENDERSON
FARABOW
GARRETT &
DUNNER ^{LLP}

1300 I Street, NW
Washington, DC 20005
202.408.4000
Fax 202.408.4400
www.finnegan.com

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art." If the Examiner applies any of the documents as prior art against any claim in the application and applicants determine that the cited documents do not constitute "prior art" under United States law, applicants reserve the right to present to the office the relevant facts and law regarding the appropriate status of such documents.

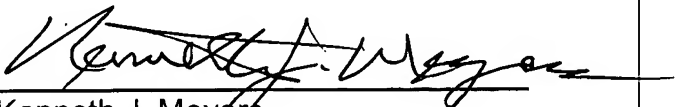
Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

If there is any fee due in connection with the filing of this Statement, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: February 20, 2004

By: 

Kenneth J. Meyers
Reg. No. 25,146
Phone: (202)408-4033
Fax: (202)408-4400
Email: ken.meyers@finnegan.com

FINNEGAN
HENDERSON
FARABOW
GARRETT &
DUNNER LLP

1300 I Street, NW
Washington, DC 20005
202.408.4000
Fax 202.408.4400
www.finnegan.com

INFORMATION DISCLOSURE CITATION

Atty. Docket No.	02356.0080-01000	Appln. No.	10/720,470
Applicant	Hilde DE REUSE et al.		
Filing Date	November 25, 2003	Group:	Unassigned

O I P E

FEB 20 2004

U.S. PATENT & TRADEMARK OFFICE

U.S. PATENT DOCUMENTS

Examiner Initial*	Document Number	Issue Date	Name	Class	Sub Class	Filing Date If Appropriate
	6,476,213	11/02	Suerbaum et al.	536	23.7	
	6,271,017	08/01	Labigne et al.	435	252.1	
	6,190,667	02/01	DeReuse et al.	424	234.1	
	6,124,271	09/00	Iversen et al.	514	44	01/23/98
	6,087,358	07/00	Baker et al.	514	230.5	09/05/97
	6,027,878	02/00	Labignet et al.	435	6	
	5,986,051	11/99	Labigne et al.	530	350	
	5,985,631	11/99	Soman et al.	435	184	09/12/97
	5,942,409	08/99	Sachs et al.	435	032	
	5,876,946	03/99	Burbaum et al.	435	7.1	06/03/97
	5,843,460	12/98	Labigne et al.	424	234.1	12/01/98
	5,695,931	12/97	Labigne	435	6	06/05/90
	5,560,912	10/96	Neeman et al.	424	195.1	06/27/94
	5,472,695	12/95	Neeman et al.	424	195.1	04/08/94
	5,441,875	08/95	Hediger	435	69.1	07/23/93
	H25	02/86	Radel	71	6	06/17/85

FOREIGN PATENT DOCUMENTS

Document Number	Publication Date	Country	Class	Sub Class	Translation Yes or No
EP 0 367 644	05/90	Europe			No
EP 0 745 674	12/96	Europe			
WO 91/09049	06/91	PCT			
WO 93/07273	04/93	PCT			
WO 94/09823	05/94	PCT			
WO 94/26901	11/94	PCT			
WO 96/33732	10/96	PCT			
WO 96/40893	12/96	PCT			

INFORMATION DISCLOSURE CITATION

Atty. Docket No.	02356.0080-01000	Appln. No.	10/720,470
Applicant	Hilde DE REUSE et al.		
Filing Date	November 25, 2003	Group:	Unassigned

FOREIGN PATENT DOCUMENTS

	Document Number	Publication Date	Country	Class	Sub Class	Translation Yes or No
	WO 98/17804	01/1998	PCT	C12N	15/31	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	International Search Report for PCT/EP99/04490, including Annex.
	Akada, J. et al., "Transcriptional Analysis of Urease Structural Gene and the UreI Gene in <i>Helicobacter pylori</i> ," <i>GUT</i> , 41:A9 (1997).
	Akada, J. et al., "European Helicobacter Pylori Study Group Xth International Workshop on Gastrointestinal Pathology and Helicobacter Pylori," <i>GUT</i> , 41(1):A7-A8 (1997).
	Chebrou, H. et al., "Amide Metabolism: a putative ABC transporter in <i>Rhodococcus</i> sp. R312," <i>Gene</i> , 182:215-218 (1996).
	Clyne et al., " <i>Helicobacter pylori</i> Requires an Acidic Environment to Survive in the Presence of Urea," <i>Infection and Immunity</i> , 63(5):1669-1673 (1995).
	Coudron, P. E. et al., "Factors Affecting Growth and Susceptibility Testing of <i>Helicobacter pylori</i> in Liquid Media," <i>Journal of Clinical Microbiology</i> , 33(4):1028-1030 (1995).
	Coudron, P. E. et al., "Use of Time-Kill Methodology To Assess Antimicrobial Combinations against Metronidazole-Susceptible and Metronidazole-Resistant Strains of <i>Helicobacter pylori</i> ," <i>Antimicrobial Agents and Chemotherapy</i> , 39(12):2641-2644 (1995).
	Coudron, P. E. et al., "Utilization of Time-Kill Kinetic Methodologies for Assessing the Bactericidal Activities of Ampicillin and Bismuth, Alone and in Combination, against <i>Helicobacter pylori</i> in Stationary and Logarithmic Growth Phases," <i>Antimicrobial Agents and Chemotherapy</i> , 39(1):66-69, (1995).
	Cussac, V. et al., "Expression of <i>Helicobacter pylori</i> Urease Activity in <i>Escherichia coli</i> Host Strains," <i>Society for Microbial Ecology and Disease</i> , 4(S):S139, Abstract H4-4 (1991).
	Cussac, V. et al., "Expression of <i>Helicobacter pylori</i> Urease Genes in <i>Escherichia coli</i> Grown under Nitrogen-Limiting Conditions," <i>Journal of Bacteriology</i> 174(8):2466-2473 (1992).
	DeCross, A. J. et al., "Metronidazole Susceptibility Testing for <i>Helicobacter pylori</i> : Comparison of Disk, Broth, and Agar Dilution Methods and Their Clinical Relevance," <i>Journal of Clinical Microbiology</i> , 31(8):1971-1974 (1993).
	Eaton, K. A. et al., "Essential Role of Urease in Pathogenesis of Gastritis Induced by <i>Helicobacter pylori</i> in Gnotobiotic Piglets," <i>Infection and Immunity</i> , 59(7):2470-2475 (1991).
	Ferrero, R. et al., "Construction of Urease Deficient Mutants of <i>Helicobacter pylori</i> By Allelic Exchange," <i>Society for Microbial Ecology and Disease</i> , 4(S):S136, Abstract H4-1 (1991).
	Ferrero, R. L. et al., "The Importance of Urease in Acid Protection for the Gastric-colonising Bacteria <i>Helicobacter pylori</i> and <i>Helicobacter felis</i> sp. nov.," <i>Microbial Ecology in Health and Disease</i> , 4:121-134 (1991).

INFORMATION DISCLOSURE CITATION

Atty. Docket No.	02356.0080-01000	Appln. No.	10/720,470
Applicant	Hilde DE REUSE et al.		
Filing Date	November 25, 2003	Group:	Unassigned

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)	
	Garcia-Rodriguez, J. A. et al., "In Vitro Activity of Six Antacids and a Urease Inhibitor Against <i>Helicobacter pylori</i> ," <i>Revista Espanola de Quimioterapia</i> , Spain, 4(4):336-337 (1991).
	Gregoriou, M. et al., "Inhibition of the Aliphatic Amidase from <i>Pseudomonas aeruginosa</i> by Urea and Related Compounds," <i>Eur. J. Biochem.</i> , 96:101-108 (1979).
	Hollaway, M. R. et al., "Chloroacetone as an Active-Site-Directed Inhibitor of the Aliphatic Amidase from <i>Pseudomonas aeruginosa</i> ," <i>Biochem. J.</i> , 191:811-826 (1980).
	Ito, Y. et al., "Ecabet sodium, a locally acting antiulcer drug, inhibits urease activity of <i>Helicobacter pylori</i> ," <i>European Journal of Pharmacology</i> , 345:193-198 (1998).
	Kühler, T. C. et al., "Structure - Activity Relationship of Omeprazole and Analogues as <i>Helicobacter pylori</i> Urease Inhibitors," <i>J. Med. Chem.</i> , 38:4906-4916 (1995).
	Labigne, A. et al., "Shuttle Cloning and Nucleotide Sequences of <i>Helicobacter pylori</i> Genes Responsible for Urease Activity," <i>Journal of Bacteriology</i> , 173(6):1920-1931 (1991).
	Labigne, A. et al., <i>Bull. Acad. Natle. Med.</i> , "Development of genetic and molecular approaches for the diagnosis and study of the pathogenesis of <i>Helicobacter pylori</i> induced gastroduodenal diseases," 175(6):791-802 (1991).
	Malanoski, G. J. et al., "Effect of pH Variation on the Susceptibility of <i>Helicobacter pylori</i> to Three Macrolide Antimicrobial Agents and Temafloxacin," <i>European Journal of Clinical Microbiology and Infectious Diseases</i> , 12:131-133 (1993).
	McGowan, C. C. et al., "The Proton Pump Inhibitor Omeprazole Inhibits Acid Survival of <i>Helicobacter pylori</i> by a Urease-Independent Mechanism," <i>Gastroenterology</i> , 107: 738-743 (1994).
	Midolo, P.D. et al., "Metronidazole resistance: A predictor of failure of <i>Helicobacter pylori</i> eradication by triple therapy," <i>Journal of Gastroenterology and Hepatology</i> , 11:290-292 (1996).
	Mirshahi, F. et al., "Omeprazole may exert both a bacteriostatic and a bacteriocidal effect on the growth of <i>Helicobacter pylori</i> (NCTC 11637) in vitro by inhibiting bacterial urease activity," <i>Journal of Clinical Pathology</i> , 51:220-224 (1998).
	Nagata, K. et al., "Inhibitory Action of Lansoprazole and Its Analogs against <i>Helicobacter pylori</i> : Inhibition of Growth Is Not Related to Inhibition of Urease," <i>Antimicrobial Agents and Chemotherapy</i> , 39(2):567-570 (1995).
	Neyrolles, O. et al., <i>Journal of Bacteriology</i> , 178(3):647-655 (1996).
	Park, J. et al., "Kinetic Studies of <i>Helicobacter pylori</i> Urease Inhibition by a Novel Proton Pump Inhibitor, Rabeprazole," <i>Biol. Pharm. Bull.</i> , 19(2):182-187(1996).
	Pope, A. J. et al., "Effect of Potent Urease Inhibitor, Fluorofamide, on <i>Helicobacter</i> sp. <i>in Vivo</i> and <i>in Vitro</i> ," <i>Digestive Diseases and Sciences</i> , 43(1):109-119 (1998).
	Scott, et al., "The Role of Internal Urease in Acid Resistance of <i>Helicobacter pylori</i> ," <i>Gastroenterology</i> 114:58-70 (1998).
	Sjostrom, J. E. et al., "Factors Affecting Growth and Antibiotic Susceptibility of <i>Helicobacter pylori</i> : effect of pH and urea on the survival of a wild-type strain and a urease-deficient mutant," <i>J. Med. Microbiology</i> , 44, 425-433 (1996).

INFORMATION DISCLOSURE CITATION

Atty. Docket No.	02356.0080-01000	Appln. No.	10/720,470
Applicant	Hilde DE REUSE et al.		
Filing Date	November 25, 2003	Group:	Unassigned

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)	
	Skouloubris, et al., "The <i>Helicobacter pylori</i> UreI Protein is not Involved in Urease Activity but is Essential for Bacterial Survival <i>in vivo</i> ," <i>Infection and Immunity</i> , 66(9):4517-4521 (1998).
	Sugiyama, T. et al., "A Novel Enzyme Immunoassay for Serodiagnosis of <i>Helicobacter pylori</i> Infection," <i>Gastroenterology</i> , 101:77-83 (1991).
	Wilson, S. A. et al., "Identification of Two New Genes in the <i>Pseudomonas aeruginosa</i> Amidase Operon, Encoding an ATPase (AmiB) and a Putative Integral Membrane Protein (AmiS)," <i>The Journal of Biological Chemistry</i> , 270(32), 18818-18824 (1995).
	Woods, M. J. et al., "Selective Inhibition and the Kinetic Mechanism of the Aliphatic Amidase of <i>Pseudomonas aeruginosa</i> ," <i>Biochemical Society Transactions</i> , 2:1344-1346 (1974).

Examiner	Date Considered
<p>*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>	
Form PTO 1449	Patent and Trademark Office - U.S. Department of Commerce